

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2007/003810

International filing date (day/month/year)
30.04.2007

Priority date (day/month/year)
19.05.2006

International Patent Classification (IPC) or both national classification and IPC
INV. A61C13/00 A61C8/00 A61C19/04

Applicant
MATERIALISE DENTAL N.V.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaag 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Salvignol, Astrid

Telephone No. +31 70 340-3094



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2007/003810

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 8, 9

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 8, 9

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2007/003810

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-7, 10-31</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-7, 10-31</u>
Industrial applicability (IA)	Yes: Claims	<u>1-7, 10-31</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

The subject matter of **claims 8 and 9** has not been searched since it relates to a method of treatment of the human or animal body by surgery (Rule 39.1(iv) PCT). By using a depth gauge, and in particular a hypodermic needle in order to measure the thickness of the soft tissue, the tissue is penetrated and altered, and this is considered as a surgical step.

Re Item V.

1 Reference is made to the following documents:

- D1 : US 5 562 448 A (MUSHABAC DAVID R [US]) 8 October 1996 (1996-10-08)
- D2: WO 2004/064660 A (TACTILE TECHNOLOGIES LLC [US]; WEINSTEIN URIEL [IL]; YOHAI YUVAL [IL];) 5 August 2004 (2004-08-05) cited in the application
- D3: US-B1-6 319 006 (SCHERER FRANZ [DE] ET AL) 20 November 2001 (2001-11-20) cited in the application
- D4: DE 100 36 027 A1 (SCHREIBER HANS [DE]) 10 January 2002 (2002-01-10)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

2.2 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):
A method for creating a personalized digital planning environment for simulation of dental implant placement from
(I) a digitised representation of an intra-oral surface anatomy of a patient including at least a part of the dental arch (e.g. video signals, column 10 lines 35 to 56, and column 24 lines 53 to 55),

(ii) a point wise digital representation of bone surface in the region of and around potential dental implant receptor sites (column 24 lines 53 to 65), and
(iii) a two-dimensional dental X-ray image of the potential dental implant receptor sites (column 25 lines 14 to 17),

the method comprising:

- mapping the two-dimensional dental X-ray image of the potential dental implant receptor sites along at least part of a dental arch of the digitized intra-oral surface anatomy (column 10 lines 57 to 67, and column 27 lines 27 to 64),
- constructing a three-dimensional surface model of the bone at the potential dental implant receptor sites based on the at least point-wise digital representation of bone surface (column 24 lines 53 to 65), and
- generating a single digital project file comprising at least the digitized representation of the intra-oral surface anatomy of the patient, the mapped two-dimensional dental X-ray image and the three-dimensional surface model of the bone at the potential dental implant receptor sites. (Column 24 line 35 to column 25 line 62)

2.3 The subject-matter of claim 1 therefore differs from this known method in that:
The three-dimensional surface model of the bone is based on a point wise digital representation of soft-tissue thickness.

2.4 Making a point wise measurement of bone surface location is equivalent to making a point wise measurement of soft-tissue thickness especially when using a stylus or probe member as in document D1. It is straightforward for the skilled person to derive one from the other. Therefore the subject matter of claim 1 is not considered to involve an inventive step.

It is to be noted that document D4 (column 6 paragraph 59) in particular shows the use of a similar probe (15) to determine soft-tissue thickness.

3 INDEPENDENT CLAIMS 19, 20, 21, 22 and 31

3.1 The method which is the subject matter of claim 1 does not involve an inventive step

based on document D1. Moreover the method disclosed in D1 is executed on a computer, implying the use of computer-related products for executing this method (in particular a computer program, a machine readable data storage device, transmission means or transmission methods and a computer system). Therefore the subject-matter of **claims 19, 20, 21 and 22** does not involve an inventive step in the sense of Article 33(3) PCT.

- 3.2 The subject matter of claim 31 basically contains all the features of claim 1 with in addition the steps of generating the data (i), (ii) and (iii) which are used in the method of claim 1. The same reasoning applies as for claim 1. Therefore the subject matter of **claim 31** also does not involve an inventive step in the sense of Article 33(3) PCT.

4 DEPENDENT CLAIMS 2-7,10-18, 23-30

- 4.1 Dependent claims 2-7,10-18, 23-30 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:
- 4.2 In document D1, a surface scan is taken and x-ray data are mapped along the surface data, and the digital data are investigated for possible dental implant receptor sites (see column 3, line 40 to column 4, line 17 of document D1). Therefore the subject matter of **claims 2, 4, 22 and 24** does not involve an inventive step.
- 4.3 From document D1 it is straightforward that data can be obtained for the entire upper or lower jaw. Therefore the subject matter of **claim 3** does not involve an inventive step.
- 4.4 It is a well-known method to obtain digital surface data from an impression of the jaw (see document D2 page 15, lines 10 to 12). Therefore the subject matter of **claim 5** also does not involve inventive step.

- 4.5 Statistical information on soft tissue thickness are known to the skilled person. Therefore it would be obvious to use these data as an alternative to local measurements.
Therefore the subject matter of **claim 6** does not involve an inventive step.
- 4.6 A method of local measurements of the thickness of soft tissue is shown in document D4 (column 6 paragraph 59). For the same reason as put forward in 2.4, the subject matter of **claims 7, 16 and 27** does not involve an inventive step.
- 4.7 The use of ultrasound measurements is well-known to the skilled person for multiple applications in the dental field (also see document D2 page 15, lines 14 to 16). It is therefore considered to be an obvious alternative to use such a method for soft-tissue thickness measurements.
Therefore the subject matter of **claim 10** does not involve an inventive step.
- 4.8 Mapping of an x-ray image along a surface scan is well-known to the person skilled in the art (see in particular documents D1, D2 and D3).
Document D1 shows the use of corresponding points on the x-ray image and on the surface anatomy for correlation (see column 27 lines 15 to 64). Therefore the subject matter of **claim 12** does not involve an inventive step.
Since the surface scan and the x-ray image are separate data acquisitions, it is obvious for the skilled person that a certain amount of folding and stretching of the x-ray image in order to be mapped along the surface image is necessary, and the way this is done is dependent on the scales, the general shape of the jaw (U shape) and the direction where from the x-ray image is usually taken (side view of the teeth).
Therefore the subject matter of **claims 11, 13, 14, 15, 25 and 26** is not considered to involve an inventive step.
- 4.9 In document D1 all the acquired and calculated digital image data are combined and displayed together on screen and used in an implant planning software (see column 4 lines 3 to 17, and column 24 line 53 to column 25 line 21).
Therefore the subject matter of **claims 17, 18, 29 and 30** does not involve an inventive step.

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International application No.

PCT/EP2007/003810

Re Item VIII.

The subject matter of claim 21 lacks clarity, since the category of the claim is not clear: the way the claim is written does not make it clear whether it is a method of transmission or a product for transmission.